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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,182	07/18/2001	Stefano Colloca	B-4175PCT 61	1087

7590

02/10/2003

Richard P Berg
Ladas & Parry
Suite 2100
5670 Wilshire Boulevard
Los Angeles, CA 90036-5679

EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 02/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,182

Applicant(s)

COLLOCA, STEFANO

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application):
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the newly amended claim 26 reads on Group I. Applicant's have cancelled any claims that read on Group II and have now presented only claims that read on Group I. The Office restricts between inventions and not claims. The Election/Restriction requirement based on the originally filed claims is still proper and is made FINAL, even though in view Applicant's amendment the Election/Restriction requirement is now moot. Group I now comprises claims 1-27 and Group II contains zero claims.

Therefore, claims 1-27 as they read on Group I are examined in the instant application.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1, is attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Additionally, in Figure 1B there is writing inside the shaded arrows, which is not legible (E4 and E1). Correction is required.

Claim Objections

Claims 22 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Any claim which is in dependent form but which is so worded that it, in fact is not, as, for example, it does not include every limitation of the claim on which it depends, will be required to be canceled as not being a proper dependent claim; and cancelation of any further claim depending on such a dependent claim will be similarly required (MPEP 608.01 (n)). Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "genetic" in the claims 1-27 is used by the claim to mean "genetic," while the accepted meaning in the context of the viral sequences is "polynucleotide

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sequence." According to Webster's dictionary the term "genic" refers to -of, relating to or being a gene-. A "gene" is defined as -a sequence of nucleotides in DNA that is located in the germ plasm on a chromosome and that is a functional unit in controlling inheritance-. As the polynucleotide sequences of interest in the invention is drawn to adenovirus which do not contain chromosomes, the preferred term would be "polynucleotide sequence" "a first polynucleotide sequence" "a second polynucleotide sequence" when referencing the two structures that are included in the cell. The sequences (units) of the invention comprise more than just a single sequence, which encodes a polypeptide (gene). The sequences comprise promoters and enhancers as well as origins of replication which are structures that are not part of a sequence which encodes a polypeptide. Amending the claim in such a way that it removed the repugnant term would render the claims allowable.

Claim 27 provides for the use of cells, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 rejected under 35 U.S.C. 102(b) as being anticipated by Alemany et al. (Journal of Virological Methods, 1997).

The instant invention is drawn to a cell comprising a “polynucleotide sequence” comprising a defective adenovirus genome having ITRs in head-to-tail configuration in which the encapsidation signal is inactivated, and at least one of the non-structural regions is inactivated.

Alemany et al. disclose a defective adenovirus in which the encapsidation signal is inactivated by a deletion of part of the packaging signal. (see figure 1, page 149). Adenovirus can circularize head to tail by its ITRs (see page 152, column 2, 2nd paragraph). This defective adenovirus is inserted into 293 cells, which then are used to assay the mini-Ad constructs (see page 153, column 2, 1st paragraph). Therefore the instant invention is anticipated.

Claim 23 rejected under 35 U.S.C. 102(b) as being anticipated by Yeh et al. (Journal of Virology, 1996).

The instant invention is drawn to a cell comprising a “polynucleotide sequence” comprising a at least one inducible promoter for the expression of the non-structural region of a deleted adenovirus.

Yeh et al. disclose a cell line 293 in which an adenoviral E4 under the control of the dexamethasone-inducible mouse mammary tumor virus long terminal repeat promoter has been introduced. Therefore the instant invention is anticipated.

Conclusion

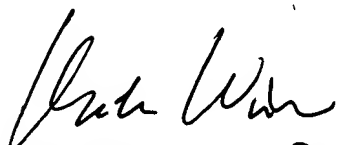
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D. 2/7/03